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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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David Lovejoy

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CANADA

EXAMINER

MACFARLANE, STACEY NEE

ART UNIT

PAPER NUMBER

1649

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/510,959	Applicant(s) LOVEJOY ET AL.	
	Examiner STACEY MACFARLANE	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-10 and 12-52 is/are pending in the application.
- 4a) Of the above claim(s) 12-33 and 35-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-10 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claim 8 has been amended as requested in the amendment filed on September 4, 2009. Following the amendment, claims 8-10 and 12-52 are pending in the instant application.

Claims 12-33 and 35-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper filed on 4/29/08.

Claims 8-10 and 34 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on September 4, 2009 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. As currently amended, Claims 8-10 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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6. As currently amended, Claim 8 is vague and indefinite in its recitation of the limitation "about 38 amino acids". Even though the use of the term "about" in a claim is inherently vague and indefinite, its use is appropriate when employed to limit a value which is composed of infinitely divisible units such as inches, meters, grams and pints where it is impractical to produce an item which has exactly the dimension recited. Even if one could practically produce an item which is exactly 1 inch in length, the length of that item is conditional upon the temperature at which it is measured. However, when defining an invention in terms of indivisible numerical units such as the number of nucleotides in a nucleic acid, the number of amino acids in a polypeptide or the number of legs on a chair or table, the term "about" is unacceptably vague and indefinite since it is practical to employ a term which possesses the required precision. If, for example, it is Applicant's intention that the claims should encompass a polypeptide of no more than 38 amino acids in length then this is exactly what the claim should recite. Whereas one would reasonably interpret the term "about one inch" as encompassing any value from 0.90 inches to 1.10 inches, one would not know if the term "about 38 amino acids" would include or exclude 30, 37, or even 40 amino acids.

7. Claim 9 stands as rejected under 35 U.S.C. 112, second paragraph, for reasons of record in the previous Office action mailed November 7, 2008.

8. On page 13 of Remarks filed September 4, 2009, Applicant traverses the rejection on the grounds that the term "amidation signal sequence" is known in the art and disclosed in US Patents 6,225,049 and 6,238,916 and, therefore, one of ordinary skill in the art would understand the metes and bounds of the term. While this has bee

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considered it is not found persuasive because neither Patent has the term "amidation signal sequence" in their claims, and both Patents explicitly define the sequence that is termed the amidation sequence within the description. Furthermore, it should be noted that the two Patents present distinct sequences as amidation signal sequences: In US Patents 6,225,049 the sequence is "PGKR", whereas in Patent 6,238,916 the sequence is "GKR". Thus, examiner maintains that the metes and bounds of the claim are indefinite.

9. Claims 10 and 34 are indefinite for depending from an indefinite claim.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 8-10 stand as rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record in the previous Office action mailed November 7, 2008.

12. On page 14 of Remarks (Id), Applicant states the following in traverse:

Applicant traverses this rejection as on the basis that the invention does not merely identify specific sequences in isolation. As stated above, the invention in one aspect has identified that a particular region of Teneurin peptides, has biological activity. This was previously unknown. Although, the Applicant has provisionally elected a "species" to be examined, it is not for the purpose of limiting the Applicant's right to the full scope of its invention and is done without prejudice to the application of the "doctrine of equivalents". The base structure is provided by SEQ. ID. NO. 69 and definitions of analog, homolog, derivative are provided for example at paragraphs [0102], [0103], and [0118] and ...Further, Applicant has amended the claim 8 without prejudice (as noted below) to indicate that the fragments are at least about 38 amino acids. Support for this can be found in the application as originally filed, for instance at paragraph [0104]. With

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regard to the Examiner's comment regarding Figure 26, please note that the description does state that rainbow trout TCAP-3 was used.

Claim 8, and depending claims, are drawn to analogs, homologs, derivatives, or a biologically active fragment of at least about 38 amino acids, of the instantly-elected sequence SEQ ID NO: 69. While the description provides a complete structure (SEQ ID NO: 69) the claims encompass partial structures, analogs, derivatives or fragments of SEQ ID NO: 69 which are "biologically active". Thus, the claims are drawn to a genus of molecules for which there is no defined structure, and which are merely described by their biological activity. There is not even identification of any particular portion of "at least about 38 amino acids" of the claimed SEQ ID NO: 69 that must be conserved for the claimed biological activity. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus and Applicant has not demonstrated possession of the genus of molecules encompassed by the claims. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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14. Claims 8 and 34 stand as rejected under 35 U.S.C. 102(a) as being anticipated by Hyseq, Inc. (2001), for reasons of record in the previous Office action mailed November 7, 2008.

On page 14 of Remarks, Applicant states in traverse:

The independent claim 1 has been amended without prejudice to include a peptide "consisting essentially of SEQ. ID. NO. 69...". As such, the claim would not comprise the much larger peptide (i.e., about 38 times larger) than the teneurin peptides of the instant invention.

Here, it is believed that Applicant means "the independent claim 8". Contrary to Applicant's argument, as currently amended, Claim 8 is drawn to an isolated peptide which consists essentially of the amino acid sequence as shown in SEQ. I.D. NO: 69, an analog, homolog, or derivative thereof or a biologically active fragment of at least about 38 amino acids thereof. Claim language amended to contain the transitional phrase "consists essentially of" limits the scope of a claim to the specified amino acids "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). MPEP § 2111.03 states:

"A 'consisting essentially of' claim occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format." *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also *Atlas Powder v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *In re Janakirama-Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. vs. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its

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specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003). (*Emphasis added*)

Given the indefiniteness of the claim as currently amended (see section 6 above), the issue of lack of written description for the claim (sections 11-12 above), and since by Applicant's own admission "the invention in one aspect has identified that a particular region of Teneurin peptides, has biological activity ... This was previously unknown" (Remarks, page 14), then the broadest reasonable interpretation of the invention is that the independent claim reads as "comprising", thereby, still encompassing larger peptides identified by the Hyseq prior art. Any additional amino acids within the prior art peptide are taken as amino acids which do not materially affect the basic and novel characteristic of the claimed invention. Thus, the Hyseq prior art anticipates this aspect of the invention and the rejection is maintained.

Conclusion

15. No Claim is allowed.

16. This application contains claims drawn to an invention nonelected with traverse in Paper filed on April 29, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M-W and F 5:30 to 2, TELEWORK-Thursdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

/John D. Ulm/
Primary Examiner, Art Unit 1649